

## **NIDDK Industry-Funded Sponsored Travel Considerations**

As part of the approval process for sponsored travel, the Deputy Ethics Counselor (DEC) must ensure the requisite conflict of interest analysis, specified by regulation, is conducted. The DEC must ensure that advice is provided to employees and the final approving official as to whether, under the circumstances, the acceptance of payment from a non-federal source would cause a reasonable person with knowledge of all the facts relevant to a particular case to question the integrity of agency programs or operations.

In making this assessment, the conflict of interest analysis for all sponsored travel involves weighing a number of factors including the identity of the non-Federal source. If acceptance of the payment from the source can reasonably be questioned, then the request for approval must be denied. While there is not a flat ban on the acceptance of payment from certain categories of donors, we recognize that the acceptance of payments from certain sources, pharmaceutical companies for example, can give rise to an appearance of impropriety. Also, HHS travel policy states that, "Authorizing officials should be very mindful of how their approval will appear to outside entities or persons who have an interest in their organization, particularly the media and Congress." There has been intense Congressional scrutiny recently of both the relationships between scientists and pharmaceutical companies and the sponsored travel of NIH scientists. Given the current climate, we generally will not recommend that sponsored travel be approved for a trip sponsored by industry. Instead, our recommendation is for the institute to fund the expenses for the trip, if it is essential to attend in person.

The following is a quote from a letter dated October 22, 2010 from Senator Charles Grassley to the National Cancer Institute (NCI). This statement is consistent with how sponsored travel is considered at NIH, and some of this language is written in a statement of functions, responsibilities, and authority of HHS' ethics program, issued by the HHS Office of General Counsel.

"Sponsored travel poses the ever-present danger of calling into question the integrity of agency programs and operations. Therefore, sponsored travel is regulated by the Administrator of the General Services Administration (GSA), in consultation with the Office of Government Ethics (OGE). 31 U.S.C. § 1353. In every case of sponsored travel, it is incumbent upon NCI management and NCI ethics officials to scrutinize, among other things, the identity of the non-Federal source, the purpose of the meeting or conference, the identities of the expected participants, the nature and sensitivity of any matter pending at NCI that may affect the interest of the non-Federal source, and the monetary value and character of the travel benefits offered. Essentially, NCI is required to ensure that each instance of sponsored travel is in the interest of the Government and that the travel relates to the NCI employee's official duties. 41 C.F.R. § 304-5.1. Even where sponsored travel is permissible, NCI should limit approval by authorizing attendance only at the portion of the event relevant to the NCI employee's duties and by limiting the type and character of the travel benefits that may be accepted."

This significant Congressional scrutiny about the use of sponsored travel by Institute employees resulted in a large data request from the NCI related to employee travel.

To elaborate a little more on the factors we consider in relation to sponsored travel, we consider things such as:

First and foremost, the identity of the sponsor is evaluated. We examine whether or not a conflict of interest exists with the sponsor, whether there could be even the appearance of a conflict, and whether there could be an appearance problem of any sort.

We analyze the duties of the traveler and whether there is a known personal outside relationship with the sponsor or any known matters pending with the sponsor (such as an award, outside activity, etc.). If the sponsor is a grantee/contractor/CRADA partner or has any other NIH relationship, we examine that as well. For example, is the travel associated with an ongoing collaboration? Specifically, the Manual Chapter for Managing Conflicts of Interests (NIH 2400-04, Section F.2) states the following for Sponsored Travel: "ICs should not accept sponsored travel for employees where they have certain official relationships, e.g., the offering organization is in the grant portfolio of an extramural Health Scientist Administrator (HSA), supplies a drug for a clinical trial the employee conducts, or is a Cooperative Research and Development Agreement (CRADA) or Materials Transfer Agreement (MTA)-CRADA partner with the employee (unless the travel was explicitly negotiated as part of the CRADA contract). In addition, sponsored travel may not be accepted by the NIH if the employee is traveling to explore potential collaborative activities with the organization, or if the employee has conducted an approved outside activity with the organization less than 12 months ago. Although official travel is governed by the regulations from the General Services Administration and sponsored travel is a gift to the NIH not to the individual, it is important to consider the potential conflicts of interest for the employee and the NIH associated with accepting sponsored travel from an outside organization."

Additionally, how will the source and nature of the travel appear to Congress, the media and the public? Can it cause NIDDK to have to defend it? For example, consider media sources such as Junketsleuth.com whose current mission it is to track and expose federal travel to see how wisely taxpayer dollars and federal resources are being spent. In these times of a deep federal deficit and intense public criticism of how we spend our time and effort, this dynamic is real and cannot be underestimated.

We also examine other factors such as:

- The purpose of the travel and its benefit to the government. For example, sponsored travel cannot be used to carry out NIH's statutory functions and regulatory functions such as site visits, investigations, inspections, audits, or performing advisory services. Also, it cannot be used to attend promotional vendor training or other meetings held for the purpose of marketing the company's products or services.
- The frequency of sponsored travel from the organization.
- The sponsor's history of reimbursing NIH on time or defaulting on reimbursements in the past. NIH has to pay for any travel expenses that go un-reimbursed.
- The location and character of the benefits offered, including the approval level required and amount of lead time prior to the trip. Foreign travel presents additional challenges.

- The cost to the government, including the cost of the employee's time away from normal duties, and the cost of funding expenses not covered by the sponsor. Would other lower-cost means suffice? (e.g. Skype - *no product endorsement intended*)
- Whether the sponsor's funds for the travel originate from HHS funding. (This is not allowed per HHS Travel Policy).
- Whether the public could be better served by providing the information in a different forum, such as a meeting open to the public held on the NIH campus. What is the most efficient and cost-effective way to accomplish the objective?

It is also important to keep in mind the following points.

- "The conflict of interest analysis prescribed by FTR 304-5.3 expressly excludes "the importance of the event to the employee or the agency" as a factor to be considered. According to the GSA, the evaluation standard does not employ a "balancing test," and the deletion of this factor found in prior versions of the FTR was intended to remove any implication that the importance of an event can override an appearance of impropriety. If acceptance of the payment from a non-Federal source under the given circumstances can reasonably be questioned, then the inquiry is at an end and the request for approval must be denied." *HHS Travel Manual, May 2008*
- Sponsored travel is reported semiannually by the Department of Health and Human Services to the U.S. Office of Government Ethics (OGE), and records are also subject to release under the Freedom of Information Act. Beginning in 2011, OGE will publish these reports on their public website ([www.usoge.gov](http://www.usoge.gov))
- Some agencies do not allow the acceptance of sponsored travel from any source.
- Acceptance of sponsored travel should be the exception, not the rule.

Currently, the acceptance of sponsored travel from industry, particularly pharmaceutical companies, is of particular concern and is risky. Activities such as using sponsored travel to attend a meeting or speak to a private group of employees from a for-profit pharmaceutical company are generally not encouraged. Investigating other no-cost means for attending the event, such as videoconferencing, is encouraged, as well as using Institute funds to travel if it is significantly important for NIDDK to have an employee attend the activity, and to attend in person.

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